# EXHIBIT A

# Comparison Of The Effectiveness Of Caricol With A Customary Papaya Fruit Pulp With Respect To The Bowel Movement Of Patients Suffering From Chronic Obstipation

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## Chronic Obstipation

In an attempt to impose some definitional uniformity for clinical research, the Rome II Committee on Functional Gastrointestinal Disorders set forth criteria for the diagnosis of chronic obstipation in 1999 which include a description of chronicity (12 weeks in the previous year, which do not need to be consecutive) and symptoms (2 of which must be present at least 25% of the time). These symptoms include: fewer than 3 bowel movements per week, hard or lumpy stools, straining with defecation, a sensation of incomplete evacuation, a sensation of anorectal obstruction, and the use of manual maneuvers to assist defecation.

## Study

Patients

N = 21 patients/inhabitants of the geriatric centre diagnosed with chronic obstipation, with majority of them being immobile, participated in this study. They received laxatives several times a week. Study excluded patients/ inhabitants who showed one or more of the following ailments

- known malignant tumor
- stoma
- blood in stool
- heart insufficiency at a high degree
- treatment with morphine

Design

After a pre-phase period of 2-3 weeks Caricol (C) and papaya pulp (P) was administered to the patients in a therapy phase of 3 weeks.

Fruit preparation

Caricol (C): a preparation from ripened papaya fruits. The ripened fruits are picked, peeled, deseeded and pureed. Citric acid is added to reduce the pH. The pulp is then subjected to a long cooking process from 30min. to 5 hours with addition of water in between. It is then cooled for minimum 30 min. in an oxygen rich atmosphere. For this study this preparation was filled in bottles and pasteurized.

Papaya pulp (P): tree ripened fruits were picked, peeled, deseeded and then pureed. In order to reduce the pH-value citric acid was added (same procedure as Caricol). The customary

papaya fruit pulp was filled into bottles and pasteurized. These bottles were then opened and stored in the fridge.

Therapy

*Pre-Phase:* all laxatives that had been administered so far were discontinued.

*Therapy Phase:* 11 patients (group C) were given Caricol (C) 2x daily 2 tbsp. before breakfast and lunch with some water. 10 patients (group P) were given papaya pulp (P) 2x daily 2 tbsp. before breakfast and lunch with some water.

During the complete period of examination the bowel reaction of the patients was documented in special stool reports. As an "escape-therapy" 2 Lecicarbon® were administered in cases where in spite of Caricol no bowel movement occurred after 3rd day. In case of no bowel movement on the 4th day 2 Clysmol® were given.

**Results**

From a total of 21 patients 3 patients of group C ad 2 from group P had a pre-phase of 2 weeks, the remaining patients had 3 weeks.

In the pre-phase 5 patients of group C had an absolutely normal bowel movement although all laxatives were discontinued. This situation prevailed in the therapy phase. Consequently these five patients were excluded from final evaluation.

Another patient of group C is continued after 2 weeks in the therapy phase.

Course of intervention

In the pre-phase 6 patients from group C were given an "escape" medication 18x which was reduced to only 6x in the therapy phase. This implies that with intake of Caricol the escape medication could be reduced by 66% (ref. Fig.1).

In group P 10 patients were given an "escape" medication 29 x in the pre-phase and still 26x in the therapy phase. Therefore, it can be inferred that intake of customary papaya fruit pulp could reduce the intervention using "escape" medication by 9% (ref. Fig.1).

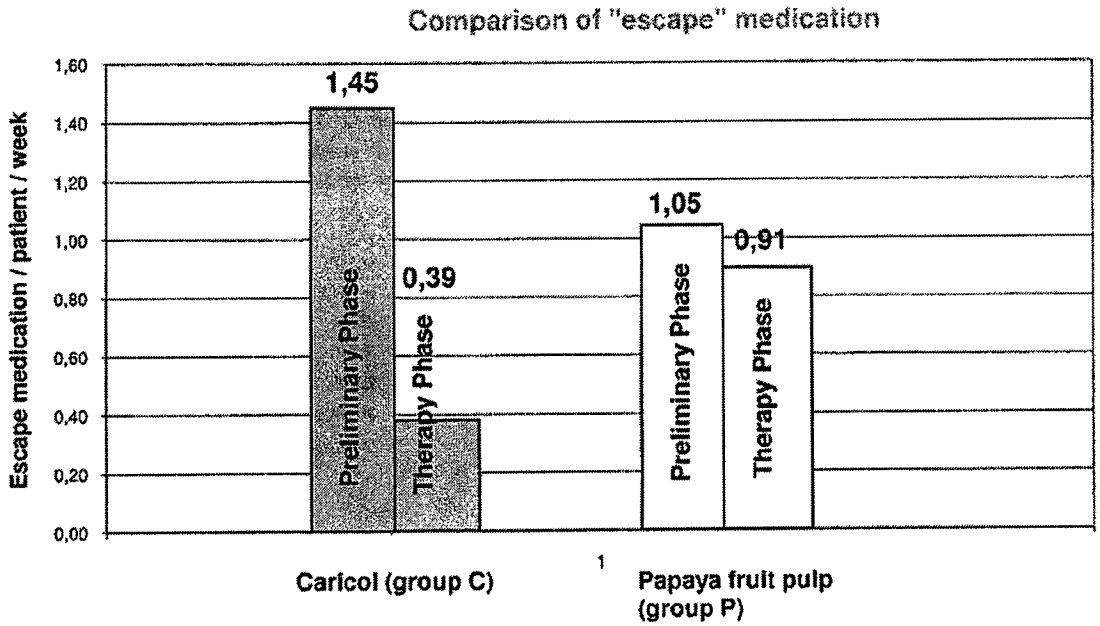


Fig. 1. A comparison of interventions, using an "escape" medication, between Caricol and a customary papaya fruit pulp therapy.

**Conclusion**

In this clinical study it could be ascertained that there was a significant improvement of bowel habit without intervention of laxatives using Caricol as compared to the customary papaya fruit pulp.